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**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

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Washington, D.C. 20231

JUL 14 1993

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fisher's Lane, Room 11-44  
Rockville, MD 20857

Dear Mr. Wilson:

The enclosed application for extension of the patent term of U.S. Patent No. <sup>4,916,213</sup>~~4,735,621~~ issued on April 5, 1988, was filed on July 2, 1993, under 35 USC § 156.

Your assistance is requested in confirming that the product identified in the application has been subject to a regulatory review period within the meaning of 35 USC § 156 (g) before its commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 USC § 156 (d)(2)(A).

Our review of the application to date indicates that the subject matter would be eligible for extension of the patent term under 35 USC § 156.

*C. E. Van Horn*

Charles E. Van Horn  
Patent Policy & Projects Administrator  
Office of the Assistant Commissioner for Patents

cc: Paul Grandinetti  
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